



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0630; FRL-9994-36]

Fluopyram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopyram in or on cranberry; lentil, dry seed; and pea, dry seed. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0630, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket

available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any

aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0630 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0630, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 21, 2018 (83 FR 65660) (FRL-9985-67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8638) by Bayer CropScience, 2.T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.661 be amended by establishing tolerances for residues of the fungicide fluopyram, N- [2- [3-chloro, -5-(trifluoromethyl)-2-pyridinyl] ethyl]-2-(trifluoromethyl) benzamide in or on cranberry at 2.0 parts per million (ppm); dry peas at 0.70 ppm; and lentils at 0.70 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing, in accordance with section 408(d)(4)(a)(i), tolerances that vary in some respects from what the petitioner requested. These variations and the Agency's underlying rationale for those variations are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special

consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopyram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopyram follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Decreased body weight and liver effects were the common and frequent findings in the fluopyram subchronic and chronic oral toxicity studies in rats, mice, and dogs, and they appeared to be the most sensitive effects. Liver effects were characterized by increased liver weight, hepatocellular hypertrophy, hepatocellular vacuolation, increased mitosis and hepatocellular necrosis. Thyroid effects were found at dose levels similar to those that produced liver effects in rats and mice; these effects consisted of follicular cell hypertrophy, increased thyroid weight, and hyperplasia at dose levels greater than or equal to 100 milligrams/kilogram/day (mg/kg/day). Changes in thyroid hormone levels were also seen in a subchronic toxicity study. In male mice, there was an increased incidence of thyroid adenomas.

Although increased liver tumors were observed in female rats in the carcinogenicity study, EPA has concluded that fluopyram is “Not Likely to be Carcinogenic to Humans” at doses that do not induce cellular proliferation in the liver or thyroid glands. This classification was based on convincing evidence that non-genotoxic modes of action for liver tumors in rats and thyroid tumors in mice have been established and that the carcinogenic effects have been demonstrated as a result of a mode of action dependent on activation of the CAR/PXR receptors. The Agency is using a point of departure for regulating fluopyram (NOAEL of 1.2 mg/kg/day) that is below the doses that cause cell proliferation in the liver (11 mg/kg/day) and subsequent liver tumor formation (89 mg/kg/day); therefore, the Agency concludes that exposure to fluopyram will not be carcinogenic.

Moreover, fluopyram is not genotoxic or mutagenic. Fluopyram is not a developmental toxicant, nor did it adversely affect reproductive parameters. No evidence of qualitative or quantitative susceptibility was observed in developmental studies in rats and rabbits or in a multigeneration study in rats. In an acute neurotoxicity study, transient decreased motor activity was seen only on the day of treatment, but no other findings demonstrating neurotoxicity were observed. In addition, no neurotoxicity was observed in the subchronic neurotoxicity study in the presence of other systemic adverse effects. Fluopyram did not produce treatment-related effects on the immune system.

Fluopyram has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Fluopyram is not a skin or eye irritant or sensitizer under the conditions of the murine lymph node assay.

Specific information on the studies received and the nature of the adverse effects caused by fluopyram as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-

observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document **Fluopyram**. Human Health Risk Assessment in Support of Tolerances without U.S. Registration on Lentils, Dry Peas, and Cranberries at pages 4 – 6 and page 12 in docket ID number EPA-HQ-OPP-2018-0630.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fluopyram used for human risk assessment is shown in the Table of this unit.

Table --Summary of Toxicological Doses and Endpoints for fluopyram for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population, including all subpopulations)	NOAEL = 50 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.50 mg/kg/day aPAD = 0.50 mg/kg/day	Acute Neurotoxicity - Rat LOAEL = 100 mg/kg/day based on decreased motor and locomotor activity in females. The LOAEL in males was 125 mg/kg/day.
Chronic dietary (All populations)	NOAEL= 1.2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.012 mg/kg/day cPAD = 0.012 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity – Rat. LOAEL = 6.0 mg/kg/day based on follicular cell hypertrophy in the thyroid, and increased liver weight with gross pathological and histopathological findings.
Incidental oral short-term (1-30 days) & Intermediate-term (1-6 months)	NOAEL= 14.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	2-generation reproduction study – Rats LOAEL = 82.8 mg/kg/day based on clinical chemistry changes and increased kidney weight in parents, and decreased body weight and body weight gain with decreases in spleen and thymus weights in offspring.
Dermal short-term (1-30 days) & Intermediate-term (1-6 months)	NOAEL= 300 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	28-day dermal study – Rat. LOAEL = 1000 mg/kg/day based on increased cholesterol (females), and increased prothrombin time (males).
Inhalation short-term (1-30 days) & Intermediate-term (1-6 months)	NOAEL= 14.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	2-generation reproduction study – Rats LOAEL = 82.8 mg/kg/day based on clinical chemistry changes and increased kidney weight in parents, and decreased body weight and body weight gain with

			decreases in spleen and thymus weights in offspring.
Cancer (Oral, dermal, inhalation)	Fluopyram is classified as "not likely to be carcinogenic to humans".		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopyram, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopyram tolerances in 40 CFR 180.180.661. EPA assessed dietary exposures from fluopyram in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for fluopyram. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM-FCID; version 3.16). The assessment is based on 100 percent crop treated (PCT) and tolerance-level residues for all commodities. Default and empirical processing factors were used in the assessment. Additionally, certain correction factors for metabolites were also incorporated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM-FCID; version 3.16). In the assessment, average field trial residues and average PCT were used. Empirical processing factors were included for processed commodities where available. Otherwise, DEEM 2018 default processing factors were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopyram does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what

percentage of the food derived from such crop is likely to contain the pesticide residue.

- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic reevaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows: almonds, 20%; apples, 25%; apricots, 5%; artichoke, 15%; broccoli, 2.5%; cabbage, 2.5%; carrots, 1%; cauliflower, 1%; cherries, 25%; cotton, 1%; dry beans and peas, 1%; grapefruit, 10%; grapes, raisins, 1%; table grapes, 5%; wine grapes, 20%; lemons, 1%; lettuce, 1%; onions, 1%; oranges, 15%; peaches, 1%; peanuts, 2.5%; pears, 5%; peppers, 5%; pistachios, 15%; potatoes, 20%; strawberries, 10%; tomatoes, 1%; walnuts, 10%; and watermelons, 15%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use are derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value,

respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluopyram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopyram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are estimated to be 50.6 parts per billion (ppb) for surface water and 97.6 ppb for ground water. For chronic exposures for non-cancer assessments, the EDWCs of fluopyram are estimated to be 17.3 ppb for surface water and 90.5 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 97.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 90.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluopyram is currently registered for use on golf course turf, residential lawns, fruit trees, nut trees, ornamentals and gardens that could result in residential exposures. EPA assessed

residential exposure using the following assumptions. For residential handler exposure, EPA assessed short-term dermal and inhalation handler exposure (derived from treating lawns by hose-end sprayers in adults). For residential post-application exposures, EPA assessed dermal exposure scenarios (for adults and children (1 to <2 years old) dermal exposure to treated turf during high contact lawn activities; for adults and youths (11 to <16 yr old) dermal exposure to treated turf during mowing and golfing activities; for children (6 to <11 years old) dermal exposure to treated turf during golfing activities; and for adults and children (6 to <11 years old) dermal exposure to treated gardens) and oral exposure (for children (1 to <2 years old) incidental oral exposure as a result of contacting treated turf). The Agency used the most conservative residential risk estimates (from the adult inhalation handler exposures from treating lawns with hose-end sprayer and from the child (1 to <2 years old) incidental oral hand-to-mouth post-application exposures to treated lawns) in the fluopyram aggregate assessment. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found fluopyram to share a common mechanism of toxicity with any other substances, and fluopyram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluopyram does not have a common mechanism of toxicity with other substances. For information regarding

EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility in the developing or young animals which were exposed during pre- or post-natal periods.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for fluopyram is complete.
- ii. There is no indication that fluopyram is a neurotoxic chemical. Although transient decreases in motor and locomotor activities in the acute neurotoxicity study were seen on the day of treatment and limited use of hind-limbs and reduced motor activity was seen in the rat chronic/carcinogenicity study, there were no other associated neurobehavioral or histopathology changes found in other studies in the fluopyram toxicity database. The effects seen in the

chronic/carcinogenicity study were in the presence of increased mortality and morbidity such as general pallor and emaciated appearance. Therefore, the reduced motor activity and limited use of hind-limbs seen in these two studies were judged to be the consequence of the systemic effects and not direct neurotoxicity. Additionally, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluopyram results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure assessment was performed using conservative exposure inputs, including tolerance-level residues for all crops, whereas the chronic dietary assessment included average field-trial residue levels for all crops. The acute dietary assessment assumed 100 PCT, whereas the chronic dietary assessment utilized average PCT numbers for several crops. Both acute and chronic dietary assessments incorporated empirical or default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopyram in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopyram.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluopyram will occupy 30% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopyram from food and water will utilize 84% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopyram is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fluopyram is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluopyram. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1500 for adults and 1400 for children (1 to <2 years old). Because EPA's level of concern for fluopyram is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, fluopyram is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluopyram.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopyram is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluopyram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (German multiresidue method DFG Method S19 and GC/MSD (gas chromatography with mass-selective detection)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for fluopyram in or on dry pea and lentil (0.7 ppm); the US tolerances being established in this rule for those commodities are harmonized with the Codex MRLs. Codex has not established an MRL for residues of fluopyram on cranberry.

C. Response to Comments

Two comments were received in response to the notice of filing. Although it is difficult to decipher the real meaning, one comment appeared to suggest that EPA focus on enforcing proper use of the pesticide by farmers and workers rather than revising tolerance regulations. The Agency directs the commenter to the Federal Insecticide, Fungicide, and Rodenticide Act, which is the existing law that provides for enforcing appropriate use of the pesticide. This tolerance rulemaking is being undertaken under the Federal Food, Drug, and Cosmetic Act, which directs EPA to establish tolerances for residues of pesticides in or on food that it determines are safe. The Agency has assessed the safety of these tolerances and made that determination, as indicated in this rulemaking and supporting documents. The second comment to the notice of filing is not

germane to this action.

D. Revisions to Petitioned-For Tolerances

The Agency is revising the commodity definition on lentils and dry peas to reflect the common commodity vocabulary currently used by the Agency. The commodity definition was revised from lentils to lentil, dry seed and dry peas to pea, dry seed. Moreover, tolerances are being established without the requested trailing zeros in accordance with the Agency's current rounding class practice.

V. Conclusion

Therefore, tolerances are established for residues of fluopyram, in or on cranberry at 2 ppm; lentil, dry seed at 0.7 ppm; and pea, dry seed at 0.7 ppm. There are currently no U.S. registrations for use of fluopyram on these commodities; these tolerances are being established to cover residues in or on these commodities that are imported into the United States.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 18, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.661, add alphabetically the entries for “Cranberry”; “Lentil, dry seed”; and “Pea, dry seed” to read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* * *
Cranberry ¹	2
* * *	* * *
Lentil, dry seed ¹	0.7
* * *	* * *
Pea, dry seed ¹	0.7
* * *	* * *

¹There are no U.S. registrations.

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